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Metrological aspects on therapeutic ultrasound parameters: effective radiating area and non-uniformity ration

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Abstract

This paper discloses the infra-structure developed aiming the implementation of the US pressure field mapping system of Inmetro's Laboratory of Ultrasound (Labus), based on current standards, which provides Brazilian traceability to related quantities. As a reliability proof of system's adequacy, the uncertainties of the effective radiating area (A_{ER}) and the beam non-uniformity ratio (R_{BN}) were assessed for US transducers in the range of 1.0 MHz to 3.5 MHz, and diameters of 1.27 cm and 2.54 cm. The calculation protocol was developed based on Standard IEC 61689:2007. Type A uncertainty was estimated from 4 repetitions of the full procedure for the determination of A_{ER} and R_{BN}, and type B uncertainty was estimated from the mathematical model for both calculation, obtained based on IEC 61689:2007 and the GUM. All results are presented herein, being maximum expanded uncertainties (95% confidence level) 6.8% for A_{ER} and 14.9% for R_{BN}.

Keywords: Therapeutic ultrasound; effective radiating area; beam non-uniformity ratio; uncertainty and standards.

1. Introduction

Soft tissue harms, as musculoskeletal injures, has been treated using Therapeutic Ultrasound (TU) in the frequency range of 1.0 to 3.0 MHz [1, 2]. Different energy and time dosages of TU are administrated to achieve clinical results, which are associated to the increase of tissue temperature up to healing levels [2, 3]. Tissue temperature increases due the intensity levels irradiated through the patient's body. However, high intensity levels can generate excessive heat, shock waves and cavitation, what can be dangerous to biological tissue [4].

As a preventive standard, the effective intensity of a physiotherapy system, determined as the quotient of the maximum ultrasonic output power (P_{out}) and the effective radiating area (A_{ER}), is limited to 3 W/cm^2 to prevent damages to the patient [4]. Besides, the ultrasonic beam distribution generated by the therapeutic treatment head is another important information concerning safety. That distribution tends to be non-uniform and, even if it was, ultrasonic propagation lead to non-uniformity at near field caused to diffraction due finite apertures. Moreover, construction details and treatment head operation can generate regions of high local pressure, also called "hot spots". Those regions may produce excessive heating in small regions of the tissue, bringing potential harmful effects to the

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patient. Non-uniformity can be quantified by the beam non-uniformity ratio (R_{BN}), a parameter that represents the ratio of the highest intensity in the field to the average intensity. Based on [4], values of R_{BN} ranging between 3 and 7 are acceptable, whilst transducer presenting $R_{BN} > 8$ are considered unsafe, and it is expected that higher values cause unwanted biological effects.

Aiming to support the assessment of TU parameters, the Brazilian National Institute of Metrology, Standardization, and Industrial Quality (Inmetro) has been putting effort on its Laboratory of Ultrasound (Labus) to provide Brazilian traceability in US transducer calibration, US power measurement and US field mapping. The later procedure is directly related to the scope of this work: measurement of A_{ER} and R_{BN}, and their respective uncertainties.

2. Material and methods

2.1. Effective Radiating Area

The Effective Radiating Area (A_{ER}) of the treatment head is calculated by multiplying the beam cross-sectional area determined 0.3 cm from the front face of the treatment head and parallel to it, $A_{BCS}(0.3)$, by a dimensionless conversion factor, F_{ac}, as presented in equation (1) [4]:

$$A_{ER} = A_{BCS}(0.3) \cdot F_{ac} . \tag{1}$$

Accordingly to [4], the conversion factor $F_{ac} = 1.354$ is used in order to derive the area close to the treatment head which contains 100 % of the total mean square acoustic pressure.

The value of each $A_{BCS}(0.3)$ is given by $n \times s^2$, where s^2 is the unit area of the raster scan and n is determined by [4]:

$$\frac{1}{M_L^2}\sum_{i=1}^{n} V_i^2 \leq \frac{0,75}{M_L^2}\sum_{i=1}^{N} V_i^2 < \frac{1}{M_L^2}\sum_{i=1}^{n+1} V_i^2 , \tag{2}$$

where V_i^2 is the peak voltage of the i-th point in the scan, N is the total number of points in the scan, and M_L^2 is the end-of-cable loaded sensitivity of the hydrophone. The M_L^2 value has been introduced for convenience in Equation (2) to convert the measured voltage to acoustic pressure. However, due to cancellation its absolute value is not required, unless phase aspects are on concern [5]. IEC 61689:2007 makes no reference to hydrophone phase, so M_L^2 cancellation is a natural consequence. Hence, the expression of A_{RE} can be written as:

$$A_{RE} = F_{ac} \cdot n \cdot s^2 . \tag{3}$$

2.2. Beam Non-uniformity Ratio

The beam non-uniformity ratio (R_{BN}) is defined as the ratio of the square of the maximum r.m.s. acoustic pressure (P_{max}) to the spatial average of the square of the r.m.s. acoustic pressure, where the spatial average is taken over the A_{ER}. R_{BN} shall be calculated as [4]:

$$R_{BN} = \frac{P_{\max}^2 A_{ER}}{\overline{pms_t s^2}} , \tag{4}$$

where s^2 is the unit area of the raster scan. The product $\overline{pms_t s^2}$ is calculated by averaging the pressure-squared values over the areas of raster scans in planes at 0.3 cm from the treatment head, and at the position of the last axial maximum (Z_N).

$$\overline{pms_t s^2} = \frac{1}{2}\left\{\left[pms_t(0.3)s^2(0.3)\right] + \left[pms_t(Z_N)s^2(Z_N)\right]\right\} \tag{5}$$

Although P_{max} and pms_t, the total mean square acoustic pressure, are referred to acoustic pressure or pressure-squared parameters, only their ratio is required for the determination of R_{BN}, hence the end-of-cable loaded sensitivity of the hydrophone is not required [4]. Based on this consideration, and knowing that:

$$pms_t = \sum_{i=1}^{N} \frac{V_i^2}{M_L^2} \text{ and } P_{\max} = \frac{V_{\max}^2}{M_L^2}, \tag{6}$$

where V_i^2 is the peak voltage of the *i*-th point in the scan, N is the total number of points in the scan, and M_L^2 is the end-of-cable loaded sensitivity of the hydrophone, R_{BN} can be expressed as:

$$R_{BN} = 2\frac{V_{\max}^2 A_{ER}}{\left[vms_t(0.3)s^2(0.3)\right]+\left[vms_t(Z_N)s^2(Z_N)\right]}, \tag{7}$$

where $vms_t = \sum_{i=1}^{N} V_i^2$.

2.3. Determination of Standard Uncertainty of Type A and Type B

According to JCGM 100:2008 [6], an instrument resolution is a Type B uncertainty, and is to be assessed taking half of the resolution value as a rectangular distribution, dividing it by $\sqrt{3}$. Herein, the finite resolution of the positioning system used to perform the raster scans is assumed to present a rectangular distribution. Hence, the Type B uncertainty of s is estimated by dividing the equipment resolution (1.25x10^{-4} cm) by $2\sqrt{3}$. The Type A uncertainty of the position system is estimated, for each of the three axes, as the standard deviation of the mean of five measurements of their linear translation.

The Type B uncertainty for amplitude measurements is estimated as the quadratic combination of three sources of uncertainty. The first one is the oscilloscope precision, defined in its manual as $0.02 \cdot V_i + 0.05 \cdot$ [vertical scale], while the second is the oscilloscope resolution estimated as $V_i / (512 \cdot 2\sqrt{3})$ for a 9-bit oscilloscope. Both of them are estimated directly by the VI. The last one is the acquisition system linearity that takes into account the linearity of the combined set hydrophone + amplifier + oscilloscope. As stipulated by IEC 61689:2007, item 6.4, this is estimated by measuring the signal received by the hydrophone and measuring system as a function of the voltage excitation applied to the transducer. Herein, we apply to an ultrasonic transducer, operating in tone-burst mode, peak-to-peak voltage excitations of 0.25 V, 1 V, 2 V, 5 V and 10 V, comprising variation of 32 dB between the lowest and highest amplitude values. Then, the signal generated by the hydrophone is measured with the aid of the oscilloscope. All measurements are performed over the last axial maximum, Z_N, and they are carried out with the four hydrophone-transducer pairs. Based on these results, the linear regression for the four pairs is determined and the root mean squared error (e_{rms}) is used as the uncertainty related to the system linearity. The Type A uncertainty for an amplitude measurement is estimated directly by the VI, as the standard deviation of the mean of five measurements, divided by $\sqrt{5}$.

Concerning noise contribution in amplitude measurements, it is noted that signals are corrected as described in [4] item B.2.4. In all cases, the signal-to-noise ratio was better than –38 dB.

The Type A uncertainty of n is estimated based on the influence of the amplitude uncertainty. The value of n is calculated by adding the amplitude uncertainty to each point of the scan, and the difference between the results, divided by 2, is assumed as uncertainty of n.

Taking into account the step size used (0.1 cm), the values of n for the transducer of 2.54 cm of diameter ($n > 300$) agree with the IEC 61689:2007 criterion, where the number of points, n, included in the determination of A_{BCS}, should be at least 100. However, this was not the case for transducers of diameter 1.27 cm ($80 < n < 100$). Hence, an uncertainty of ± 1.0 %, due to the selected step size, is included in the A_{ER} uncertainty determination for both transducers sizes [7]. Moreover, the uncertainty due to spatial-averaging is considered to be ± 1.0 %, also based on [7]. It is of note that spatial averaging corrections (c_{sa}) are calculated at the Z_N position for hydrophone-transducer combinations, as defined in [8] (Annex J, item J.2), and their values are considered to correct the V_{max} amplitude.

Based on [4], the standard deviation of F_{ac} in the mean value is approximately 0.09, for a sample size of 66 points. Consequently, the Type B uncertainty of F_{ac} is estimated to be $0.09/\sqrt{66}$. Moreover, the uncertainty due to truncation of the raster scan is assumed to be ± 0.6 %, based on [7].

Combination of the above Type A and B components gives the overall combined uncertainty of A_{ER} and R_{BN}. Calculations are incorporated within the VI, and determined for each one of the four repetitions of a complete procedure. Therefore, the highest value of the combined uncertainties from each one of the four repetitions is combined with the Type A uncertainty of the whole process, to give the final combined uncertainty of the whole measurement.

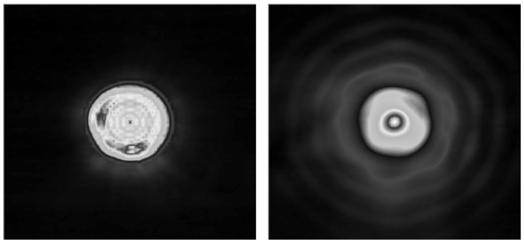
2.4. Ultrasonic Pressure Field Mapping System

The typical system configuration used during the mapping acquisition is composed by a personal computer connected to the oscilloscope, to signal generator, and to the moving controllers located on the water tank. Hence, Labus is structured with a water tank measuring 1700 mm x 1000 mm x 800 mm, enough to perform most usual measurements and calibrations in the megahertz frequency range. The specified positioning system, used to move the transducer in the water tank, presents X and Y axes, both with a moving range of 300 mm, and a Z axis, 600 mm long (Newport Corporation, Irvine, CA, USA). Each axis presents a resolution and repeatability of 1.25 µm. Additionally, there is a 360^o rotation system, with a resolution of 0.01^o. The needle hydrophones used during the mapping procedure present active elements of 0.2 mm and 0.5 mm (Precision Acoustics Ltd., Dorchester, Dorset, UK). Transducers are excited using 30-cycles burst of sine wave generated by the function generator AFG 3252 (Tektronix, Beaverton, Oregon, USA), and the waterborne signal were acquired using the oscilloscope TDS 3032B (Tektronix, Beaverton, Oregon, USA).

Aiming to integrate all system components, and also to furnish a friendly interface, a virtual instrument (VI) was developed in LabVIEW (National Instruments Corporation, Austin, TX, USA) [9]. The VI allows controlling all axes movements, acquiring waterborne signals, and calculating the essential parameters to assess and calibrate US transducers. Besides, the software also performs automatically the raster scans necessary to calculate the parameters related to physiotherapy US transducers, based on [4].

3. Results

The A_{ER} and R_{BN}, and respective uncertainties were determined for US transducers in the range of 1.0 MHz to 3.5 MHz, and diameters of 1.27 cm and 2.54 cm. The transducers were mapped over two planes at 0.3 cm from the treatment head face, and Z_N, presenting 80 x 80 mm of dimension, and using a step of 1.0 mm. Both mappings were repeated 4 times, and the A_{ER} and R_{BN} mean values were calculated (Table 1). An example of planes mapped at 0.3 cm of the transducer face and at Z_N, for one of the repetitions, is presented on Fig.1.



(a) (b)

Fig.1 Results obtained for 1.0 MHz transducer (Ø = 2.54 cm), during repetition 3: planes mapped (a) at 0.3 cm of the transducer face, and (b) at Z_N. The A_{ER} value calculated is 4.67 cm^2, and R_{BN} value is 3.20.

The A_{ER} average values for the transducers of 1.27 cm^2, and frequencies of 1.0 MHz and 2.25 MHz, were 1.18 cm^2 and 1.15 cm^2, respectively. Considering the transducers of 2.54 cm^2, and frequencies of 1.0 MHz and 3.5 MHz, the A_{ER} average values were 4.22 cm^2 and 4.69 cm^2, respectively (Table 1). Concerning R_{BN}, all values were inferior to 3.51 (Table 2). Besides, the results pointed out expanded uncertainties inferior to 6.8% for A_{ER} and 14.9% for R_{BN}.

Table 1. Values of A_{ER} determined for two transducers of 1.27 cm of diameter, and frequencies of 1 MHz and 2.25 MHz, and two transducers of 2.54 cm of diameter, and frequencies of 1 MHz and 3.5 MHz. Respective type A, type B, and expanded uncertainties are also presented.

	Ø of 1.27 cm		Ø of 2.54 cm	
	1.0 MHz	2.25 MHz	1.0 MHz	3.5 MHz
A_{RE} – Mean (cm^2)	1.18	1.15	4.22	4.69
$u_{type\ A}$ (cm^2)	2.50x10^{-3}	1.25x10^{-2}	1.89x10^{-2}	8.29x10^{-3}
$u_{type\ B}$ (cm^2)	3.14x10^{-2}	3.66x10^{-2}	8.95x10^{-2}	8.45x10^{-2}
$u_{combined}$ (cm^2)	3.15x10^{-2}	3.86x10^{-2}	9.15x10^{-2}	8.49x10^{-2}
Coverage factor	2	2	2	2
$u_{expanded}$ (cm^2)	6.3x10^{-2}	7.9x10^{-2}	1.9x10^{-1}	1.7x10^{-1}
$u_{expanded}$ (%)	5.5	6.8	4.5	3.6

Table 2. Values of R_{BN} determined for two transducers of 1.27 cm of diameter, and frequencies of 1 MHz and 2.25 MHz, and two transducers of 2.54 cm of diameter, and frequencies of 1 MHz and 3.5 MHz. Respective type A, type B, and expanded uncertainties are also presented.

	Ø of 1.27 cm		Ø of 2.54 cm	
	1.0 MHz	2.25 MHz	1.0 MHz	3.5 MHz
R_{BN} – Mean	3.24	2.76	3.25	3.51
$u_{type\ A}$	2.01x10^{-2}	3.43x10^{-2}	3.06x10^{-2}	3.33x10^{-2}
$u_{type\ B}$	2.25x10^{-1}	2.01x10^{-1}	2.00x10^{-1}	2.19x10^{-1}
$u_{combined}$	2.26x10^{-1}	2.03x10^{-1}	2.02x10^{-1}	2.21x10^{-1}
Coverage factor	2.0	2.0	2.0	2.0
$u_{expanded}$	4.6x10^{-1}	4.1x10^{-1}	4.1x10^{-1}	4.5x10^{-1}
$u_{expanded}$ (%)	14.2	14.9	12.6	12.8

4. Discussion

For all 4 transducers tested, it was observed that A_{ER} type B uncertainties were higher than type A ones. Also, it was noted that type A uncertainties were of the same magnitude (absolute value) either for 1.27 cm and 2.54 cm of diameter, what lead to a natural higher relative value for 1.27 cm transducer. On the other hand, type B grows proportionately to transducer diameter, as expected. Those are the main reason for the lower relative (%) expanded uncertainty for the 2.54 cm transducer.

An equivalent analysis arises for R_{BN} observing Table 2. Type B uncertainties were found higher for larger diameters. Besides, a nothing but noticeable high uncertainty (both type A and B) can be observed for higher frequency transducers of the same diameter. However, expanded uncertainties ranging from 12% to 14.9% in all cases bring to light the fact that the presented R_{BN} uncertainty budget is quite device independent. It has not been found in the literature data to compare with the results presented in this paper for R_{BN}.

Analysing the uncertainty contributions of A_{RE} calculation, one can observe that the greatest contribution comes from n. The uncertainty value of n was estimated based on amplitude uncertainty values, thus better values of u_n could be achieved by improving u_{V_i}. Moreover, F_{ac} also presents high uncertainty values. As mentioned before, the F_{ac} uncertainty was obtained as "suggested" by IEC 61689:2007. That means the empirical value given to F_{ac}, as it was determined, is an important source of uncertainty. We point out that these two sources of uncertainty had not previously been considered in the literature. Further, if these sources of uncertainty were excluded from our uncertainty budget, the expanded uncertainty of A_{ER} presented here would be reduced by almost 3 %.

For R_{BN}, the most important uncertainty sources are those derived from the V_{max} Type B uncertainty and the combined uncertainty of A_{ER}. It is observed that the instrumentation is a limiting factor, as the oscilloscope is responsible for high Type B uncertainty values. This uncertainty could be reduced by changing the instrument or the method applied to measure voltage amplitude values. Despite the significant contribution from these sources of uncertainty, the expanded uncertainty obtained for R_{BN} was considered adequate in terms of IEC 61689:2007, which specifies $u_{R_{BN}} < \pm 15\,\%$, 95 % confidence level.

5. Conclusion

The ultrasonic pressure field mapping system developed at Labus – Inmetro is capable of carrying out mappings and calculations need to determine the parameters related to the ultrasonic beam of transducers used in physiotherapy, based on IEC 61689:2007. Moreover, the expanded uncertainties achieved for A_{ER} (7%) and R_{BN} (15%) (95% confidence level), using transducers of different diameters (1.27 cm and 2.54 cm) and frequencies (1 MHz to 3.5 MHz), are lower than the ones pointed out in [4, 10]. Hence, Labus is prepared to estimate A_{ER} and R_{BN}, and respective uncertainties, playing its role for mot let unsafe equipment to be certified, as for those safe accordingly the criteria not be penalised.

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